

Applicant : Shohei Koide  
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Attorney's Docket No.: 17027.003US1

### REMARKS

Applicant respectfully requests entry of the amendments and remarks submitted herein.

#### The 35 U.S.C. § 102(e) & § 103(a) Rejection of the Claims

The Examiner rejected claims 1, 4, 7-8, and 55-57, 59-63, and 64-79 under 35 U.S.C. § 102(e) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Lipovsek (U.S. Patent No. 6,818,418) for reasons set forth by the Board's decision on June 9, 2009 and reiterated in the current Office Action mailed September 16, 2009. As this rejection may be maintained with respect to the pending claims, Applicant respectfully traverses this rejection of the claims.

Claim 1 has been amended to incorporate the language of claim 65, and claim 57 has been amended to incorporate the language of claim 79 so that the modified human Fn3 molecules have Arg at amino acid residue 6. New claims 80-82 reflect the incorporation of claims 56 and 71 into the language of claim 1 so that the Fn3 molecules include a stabilizing mutation, which mutation is a substitution of Asp 7 or Asp 23 with a positively charged amino acid residue.

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Dillon*, 919 F.2d 688, 16 U.S.P.Q.2d 1897, 1908 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

The Supreme Court has set out the analysis for patentability under 35 U.S.C. § 103(a): the scope and content of the cited documents are to be determined; differences between the cited documents and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. (see, e.g., *Graham v. John Deere Co.*, 383 U.S. 1 (1966) and *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007)) Further, the cited documents must be

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considered in their entirety, and it is not permissible to pick and choose from any one document only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such document fairly suggests to one of ordinary skill in the art. (see, e.g., *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 U.S.P.Q. 416 (Fed. Cir. 1986) and *In re Wesslau*, 353 F.2d 238, U.S.P.Q. 391 (C.C.P.A. 1965)) The scope and content of the cited documents and the differences between the cited documents and the claims at issue are discussed hereinbelow, as are the reasons the claims are not obvious in view of the cited documents.

Figure 4 of Lipovsek presents a sequence alignment between a fibronectin type III protein domain with sequences that are stated to be fibronectins from other sources, as well as sequences of related proteins. (see Figure 4, column 6, lines 31-33 and column 9, lines 9-12) The first row of Figure 4 depicts Hs FND (human fibronectin type III domain). Rows 2-9 depict alleged fibronectin sequences from other non-human sources (e.g., cow (row 2), rabbit (row 5), frog (row 7), dog (row 8) and horse (row 9). Rows 10-16 depicts sequences of other proteins (i.e., tenascin-C (row 10), tenascin precursor (row 11), collagen alpha precursor (row 13), collagen type 12 (row 14) and undulin 1 (row 16).

Applicant submits that the sequences presented in rows 10-16 of Figure 4 of Lipovsek are not Fn3 molecules. Further, the only human sequence presented in rows 1-9 is the human fibronectin type III domain sequence itself. The other sequences presented in rows 2-9 are not human Fn3 sequences but instead are unmodified wild-type fibronectin sequences from other animals (e.g., cow, dog, horse, pig, rabbit or frog). With respect to the claimed modified Fn3 molecules having a stabilizing mutation and having Arg at amino acid residue 6, Applicant submits that such Fn3 molecules are neither anticipated by nor obvious in view of Lipovsek. With respect to the claimed modified Fn3 molecules having a stabilizing mutation, which mutation is a substitution of Asp 7 or Asp 23 with a positively charged amino acid residue, Applicant submits that such Fn3 molecules are neither anticipated by nor obvious in view of Lipovsek.

With respect to claims 65 and 79, which have been incorporated into claims 1 and 57, the Examiner alleges at page 11 of the Office Action that these claims are obvious in view of the HsFND sequence of Figure 4 of Lipovsek. However, the HsFND sequence of Figure 4 of

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Lipovsek is the Homo sapiens fibronectin type III domain and does not comprise the recited stabilizing mutation.

With respect to claims 67, which has been incorporated into claim 1 (now claims 80 and 81), the Examiner alleges at page at page 11 of the Office Action that claim 67 is anticipated by Lipovsek wherein position 7 is val or asn. However, claims 67 recited that Asp 7 is substituted with a positive amino acid. Thus, Lipovsek does not anticipate claims 80 or 81.

With respect to claim 71, which has been incorporated into claim 1 (now claims 80 and 82), the Examiner alleges at page at page 12 of the Office Action that it would have been within ordinary skill in the art to substitute one amino acid in one or more positions from the homologous Fn3. Applicant respectfully submits that even if it would have been within ordinary skill in the art to substitute one amino acid in one or more positions from the homologous Fn3, that finding alone would not render claim 71 obvious, and the Examiner has not provided evidence to modify any of the Lipovsek molecules to arrive at the claimed molecules. Applicant submits that the Office Action does not provide citation(s) sufficient to support the obviousness rejection and submits that the Examiner is taking "official notice." If the Office maintains the rejection, under 37 C.F.R. § 1.104(d)(2), the Examiner is requested to provide an affidavit setting forth specific factual statements and explanation to support the finding. Thus, if the Office maintains the rejection in the next communication, Applicant respectfully requests that the Examiner provide an affidavit setting forth specific factual statements and explanations to support the conclusion that claims 80 and 82 are obvious.

Thus, Applicant submits that Lipovsek does not disclose each element of the claim under consideration, and a person of ordinary skill in the art would recognize differences between the claimed invention and the reference disclosure. Accordingly, because there are tangible differences between the invention as claimed and Lipovsek, Applicant submits that Lipovsek does not anticipate the currently pending claims. Further, for the reasons explained hereinabove, the Examiner has not provided evidence that the claims are obvious in view of Lipovsek. Accordingly, Applicant requests that the Examiner withdraw the this rejection of the claims.

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**CONCLUSION**

The Examiner is invited to contact Applicant's Representative at the below-listed telephone number if there are any questions regarding this Response or if prosecution of this application may be assisted thereby. If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 50-3503. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fees to Deposit Account 50-3503.

Respectfully submitted,

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By their Representatives,

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Date:

December 16, 2009

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